Background

- Under the Hatch-Waxman law passed in 1984, generic approval is allowed when a new drug's patent and market exclusivity protection expires, or when a 30-month stay terminates. The intent of the law is to provide incentives to develop valuable new drug treatments through patent and exclusivity protection, but also to facilitate access to generic versions of the drug after the innovator's patent or exclusivity expires.

- In recent years, however, access to generic drugs has sometimes been delayed by litigation. President Bush took regulatory action earlier this year to close many of the loopholes in the implementation of the Hatch-Waxman law, which will save all Americans an estimated $35 billion over ten years. The provisions in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 , as signed by the President on December 8, 2003,write these executive actions into law, and take additional steps to reduce or eliminate the delays in the movement of generic drugs to the marketplace. As a result, patients will benefit from greater and more predictable access to safe, effective, low-cost generic alternatives to brand name medicines.

Medicare legislation that passed as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 will:

- Lower prescription drug costs for millions of Americans by improving access to generic drugs, which are safe and effective and can be much less costly alternatives to brand-name prescription drugs.

- Close loopholes in the implementation of the Hatch-Waxman law, which governs how generic drugs can compete with brand-name drugs. As a result, patients will benefit from faster and more widespread access to safe, effective, low-cost generic alternatives to brand-name drugs.

- Help reduce expensive lawsuits over drug patents and make the generic drug approval process more efficient. It will also help to lower national health care costs by reducing the cost of bringing safe and effective generic drugs to market.

Key provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 will:

- **Place limits on current law that enabled drug manufacturers to extend drug patents by providing for only one 30-month automatic stay at most in patent infringement litigation involving a generic drug application.** Drug manufacturers would be limited to only one 30-month stay per generic application, to resolve allegations that a generic drug maker is infringing a drug patent. This Act builds on a regulation issued by the Administration earlier this year.

- **Provide enhanced incentives to develop generic drugs and increase generic competition.** The Act clarifies the existing incentive of 180 days of exclusive marketing rights for the first generic company that obtains approval of a generic drug. By allowing the faster introduction of multiple generic versions of a drug, more competition and lower prices will result.

30-Month Stay Provisions

- Limits a brand name drug manufacturer to one FDA 30-month stay of competition due to a patent infringement suit against a generic drug applicant. In the past, brand name companies that faced expiring patents on their drugs could obtain new patents that could lead to additional 30-month delays. These multiple 30-month stays, which have led to delays in generic drug marketing of up to three and a half additional years, would not be permitted under the Act.

- Permits a generic applicant being sued to file a counterclaim to correct or delete patent information that does not protect the drug.

- Clarifies how the process of generic applicants' challenges to brand name drug patents works. Over the years, the unclear language of the law has led to many lawsuits that have independently delayed approval of less expensive generic drugs.

- Permits a generic drug applicant to seek a declaratory judgment to settle the status of outstanding patents prior to marketing a drug.

Enhanced Generics Competition Provisions (180 Day Exclusivity)

- Refines and clarifies the existing incentive for a generic company to seek approval: once approved, the first applicant will be the only company with a generic product for 180 days.

- A first generic drug applicant would forfeit its 180-day market exclusivity if it did not market in a timely manner its product once it was able to do so. This

limitation on “sitting on an approval” will prevent first generic marketers from keeping subsequent generic applicants out of the market.